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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/638,241	08/14/2000	Bret A. Ferree	BAF-11802/29	9686

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EXAMINER

HO, UYEN T

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/638,241

Applicant(s)

FERREE, BRET A.

Examiner

(Jackie) Tan-Uyen T. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s) 9.
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II, claims 12-18 in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 2/26/2001 and 7/13/2001 have been considered by the examiner.

Terminal Disclaimer

3. The terminal disclaimer filed on 3/6/2003 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Specification

4. The abstract of the disclosure is objected to because it contains phrases which can be implied such as "The device ... according to the invention". Correction is required. See MPEP § 608.01(b).

5. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract

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on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Drawings

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 1702, 1806', 2102, 2104 and 2302. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: 108, 808 and 1804. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

8. The disclosure is objected to because of the following informalities: Page 5, "Figure 10A" should be "Figure 10." Appropriate correction is required.

Claim Objections

9. Claim 17 is objected to because of the following informalities: "The method of claim 16, including a hydrogel or elastomer" should be "The method of claim 16, wherein the device includes a hydrogel or elastomer". Appropriate correction is required.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 12-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Haldimann (6,428,576).

In regard to claim 12, Haldimann discloses a method of preventing the escape of natural material through a defect in the annulus fibrosus of a spinal disc comprising the steps of: inserting a device (1) relative to a defect in an annulus fibrosis (3, fig. 1) and

occluding the defect by allowing the device (1) to solidify (col. 5, line 14 to col. 7, line 44).

In regard to claim 13, the method of claim 12, wherein the step of inserting device (1) includes compacting the device into a compressed form for introduction relative to the defect, is inherent. Col. 5, line 13 to col. 6, line 19 and 12, line 19 to col. 17, line 25, Haldimann discloses the device 1 being made of hydrogel or cured polymers in a liquid or semi-solid, elastic, visco-elastic form and being injected into the defect area by a needle or injection cannula to conform and fill the defect and cure to a solid hydrogel (expanded) form. In semi-solid, elastic or visco-elastic form, the device or sealant is inherently in compressed form for introducing to a treatment site through a needle or a cannula tip and the device is in an expanded form when it comes out from the needle or the cannula tip as it fills the defect area and cures to a solid hydrogel form.

In regard to claim 14, wherein the device includes a patch (1, fig. 1 and also in col. 9, lines 52-64, Haldimann discloses the device 1 patches up the defect in an annulus fibrosus). Note: the definition of "patch" is a piece of material used to mend or cover a hole or a weak spot. The term "patch" does not impose any structural limitations on the claims distinguishable over the Haldimann's device.

In regard to claim 15, Haldimann discloses the method of claim 12, including the step of anchoring each device in place relative to the defect. In col. 9, lines 1-11 and col. 10, lines 13-34, Haldimann discloses the device (1) having a property of interlocking with the natural tissue at the application site and helps to mechanically secure the

device with the applicant site during curing time. Note: the definition of "anchoring" is holding in place or securing firmly or becoming fixed.

In regard to claim 16, Haldimann discloses the method of claim 12, wherein the device (1) includes a liquid or gel which solidifies following injection into the defective area (col. 7, lines 20-44).

In regard to claim 17, Haldimann discloses the method of claim 16, wherein the device includes a hydrogel or elastomer (col. 7, lines 20-44).

In regard to claim 18, Haldimann discloses the method of claim 12, wherein the device occludes the defect while allowing compression and distraction of the disc with respect to normal spinal movement (see col. 11, lines 7-56).

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Haldimann (US2002/0198599 A1) discloses a device and method for repairing a defect in an annulus fibrous.

Ross et al. (6,436,143) disclose a method of treating an intervertebral disk including the steps of: injecting an expandable member into annulus fibrosus then injecting a thermoplastic material into the annulus fibrosus.

Guagliano et al. (6,206,921) and Ross et al. (6,183,518) disclose a method for repairing the annulus fibrosus and replacing the nucleus pulposus.

Sharkey et al. (6,126,682) disclose a method for treating annular fissures.

Felt (5,556,429) and Felt et al. (5,888,220) disclose a method of repairing and replacement of the intervertebral disc of a spine using a curable biomaterial.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



(Jackie) Tan-Uyen T. Ho
Patent Examiner
Art Unit 3731
March 20, 2003